June 14, 2000

Jane E. Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Petition to Amend Regulations Concerning Allergenic Substances

Dear Commissioner Henney:

On May 26, 2000, Attorneys General from nine states[1] petitioned the Food and Drug Administration (FDA) to amend its regulations concerning allergenic substances.[2] We strongly support that petition and urge the agency to focus immediate attention on this important public health issue.

Food allergies are becoming increasingly prevalent in the United States. Up to 8% of children less than three years of age and approximately 2% of the adult population suffer from food allergies.[3] In some cases, foods can cause anaphylaxis, which, if untreated, can cause death in minutes. Food causes an estimated 2,500 anaphylactic reactions in the United States each year, resulting in approximately 125 deaths.[4]

Even a minuscule amount of an allergen may cause a severe reaction. As the FDA recognized in its Consumer Magazine, as little as one-five-thousandth of a teaspoon of an allergen has caused death.[5] Since there is no preventative medical treatment available, the only option is to avoid consuming the allergen. Unfortunately, that is not always possible for two main reasons.

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[1] The Attorneys General from the following states have signed the petition: New York, Maryland, Michigan, Wyoming, Ohio, Tennessee, Connecticut, Vermont, and Massachusetts.

[2] The petition focuses on the most common allergens: milk, eggs, fish, crustacea, mollusks, tree nuts, wheat, peanuts, and soybeans.

[3] Hugh A. Sampson, *Food Allergy. Part 1: Immunopathogenesis and Clinical Disorders*, 103 J. ALLERGY CLIN. IMMUNOL. 717 (1999).

[4] A. Wesley Burks & Hugh A. Sampson, *Anaphylaxis and Food Allergy*, 17 CLIN. REV. IN ALLERGY AND IMMUNOL. 339 (1999).

[5] *Food Allergies: Rare but Risky*, FDA CONSUMER MAGAZINE, Dec. 1993, at 94.

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First, consumers cannot rely on the food label to provide complete information. Food labels often fail to declare allergens by name when they are used in flavorings or are incidental additives. In addition, food labels often fail to declare allergens when they are introduced into a food that is processed on shared equipment or when "re-work" is added from one product to another.[6] In one documented case, sunflower butter became contaminated with peanut butter that was manufactured on shared equipment and caused an allergic reaction in a peanut-sensitive patient.[7] Similarly, a fish-allergic individual died from ingesting french fries that had been fried in oil previously used to fry fish.[8]

Second, consumers cannot always obtain information about flavorings and incidental additives by contacting the manufacturer. Many manufacturers do not include their telephone number on the food label. Even when telephone numbers are available, consumers are faced with the daunting task of contacting each individual company and speaking with customer-service representatives who may be uninformed about the content of flavorings and the presence of incidental additives. In addition, because companies may change their manufacturing practices, a food that is allergen-free one week may not be allergen-free the next.

In recognition of the problem of undeclared allergens in food, the FDA issued a Notice to Food Manufacturers in 1996 urging them to "examine their product formulations for ingredients and processing aids that contain known allergens... and to declare the presence of such ingredients...."[9] Later that same year, Commissioner David Kessler wrote a letter to the National Food Processors Association to reiterate the need for allergen labeling.[10] Kessler declared the issue a "major public health problem" and described cases of adverse reactions and death due to undeclared allergens in food.

Despite the agency's requests for voluntary action, Class I recalls continue to rise at an alarming rate. Therefore, it is clear that mandatory regulations, as proposed by the Attorneys

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[6] Susan Hefle, *Impact of Processing on Food Allergens*, 459 ADV. EXP. MED. BIOL. 107 (1999).

[7] *Id.* (citing J.W. Yunginger et al., *Use of Radioimmunoassay to Determine the Nature, Quantity, and Source of Allergenic Contamination of Sunflower Butter*, 46 J. FOOD PROT. 625 (1983)).

[8] *Id.* (citing J. W. Yunginger et al., *Fatal Food-Induced Anaphylaxis*, 260 JAMA 1450 (1988)).

[9] Fred R. Shank, Director, Center for Food Safety and Applied Nutrition, Notice to Manufacturers, *Label Declaration of Allergenic Substances in Foods* (June 10, 1996).

[10] Letter from David A. Kessler, Commissioner, Food and Drug Administration, to John Cady, President and CEO, National Food Processors Association (Dec. 11, 1996).

General's petition, are necessary. Good Manufacturing Practice (GMP) regulations should be amended to prevent cross-contamination in the first place. In addition, regulations should require food labels to alert consumers when allergens are present in a food -- regardless of the source or amount of the allergen. Labeling, however, must not be used in lieu of improving GMPs.

We believe that the regulatory proposals set forth in the Attorneys General's petition will increase the food choices of allergic consumers and reduce the incidence of illness and death resulting from the inadvertent consumption of allergenic substances. We urge the agency to act expeditiously on this matter.

Sincerely,

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